Docket No.: 080623-0484 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of	:	Customer Number: 41552
BATCH, RICHARD M.	:	Confirmation Number: 3293
Application No.: 10/726202	:	Tech Center Art Unit: 3735
Filed: December 01, 2003	:	Examiner: Christine d. Hopkins

For: SYSTEM AND METHOD FOR ANALYZING MEDICAL TREATMENT DATA

TRANSMITTAL OF APPEAL BRIEF

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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I hereby certify that this correspondence is being electronically-transmitted to the United States Patent and Trademark Office on **Aug 21, 2008.**
/Ta'Loria Simms/
Ta'Loria Simms

Sir:

Submitted herewith is Appellant's Appeal Brief in support of the Notice of Appeal filed April 21, 2008. Please charge the Appeal Brief fee of $510.00 to Deposit Account 502624.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due under 37 C.F.R. 1.17 and 41.20, and in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,
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Sir:

This Appeal Brief is submitted in support of the Notice of Appeal filed April 21, 2008, wherein Appellant appeals from the Primary Examiner's rejection of claims 1-6, 8-17 and 19-23.

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I. REAL PARTY IN INTEREST

The real party in interest in this application is Cardinal Health 303, Inc., having been originally assigned to Alaris Medical Systems, Inc. It is noted that Alaris Medical Systems, Inc. changed its name to Cardinal Health 303, Inc., by assignment recorded on January 24, 2006, at Reel 017056, Frame 0713.

II. RELATED APPEALS AND INTERFERENCES

The Appellants are unaware of any related appeals and interferences.

III. STATUS OF CLAIMS

Claims, 1-6, 8-17 and 19-23 are pending in this application and have been finally rejected. It is from this final rejection of claims 1-6, 8-17 and 19-23 that the appeal is taken. These claims are copied in the Claims Appendix to this Appeal Brief.

IV. STATUS OF AMENDMENTS

A response was filed subsequent to the Final Office Action of November 21, 2007. No claims were amended in the response to the Final Office Action. However, it is noted that in the Advisory Action, the Examiner withdrew the rejection of claims 1-11 under 35 U.S.C. §112, first paragraph. Hence, only the rejection of the claims based on 35 U.S.C. §102 remain.

The claims copied in the Claim Appendix correspond to the claims provided in the response to the Final Office Action filed on February 14, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 of the application relates to a medical treatment data analysis system 4 (See Fig. 1), that analyzes medical treatment data associated with medical treatments for a plurality of patients to determine a medical treatment guideline based on actual treatment of a plurality of patients, and for updating at least one medical device 255 (See Fig. 8) that is in communication with the system 4 with the guideline. See also paragraph [00041]. As recited in paragraph [00081] and depicted in Figure 8, a memory 260 is providing for storing medical treatment data associated with medical treatments actually delivered to a plurality of patients. The medical treatment data includes a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter. This is further discussed in paragraph [00083].

A processor 265 is operatively connected to the memory 260 and is configured to compile from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter. Again, see Fig. 8 and paragraph [00083]. The processor analyzes the compiled treatment parameter values, and determines a medical treatment guideline in accordance with the analysis. See paragraph [00083]. A medical treatment guideline represents acceptable values for the selected treatment parameter. The processor automatically supplies the medical device 255 with at least one revised treatment guideline. See also, paragraph [00085].

Claim 23 is similar to claim 1. Hence, claim 23 relates to a medical treatment data analysis system 4 (see Fig. 1) that analyzes medical treatment data associated with medical treatments for a plurality of patients to determine a medical treatment guideline based on actual treatment of a plurality of patients, and for updating at least one medical device 255 (see Fig. 8) that is in communication with the system 4 with the guideline. See also paragraph [00041]. As recited in paragraph [00081] and depicted in Figure 8, a memory 260 is providing for storing medical treatment data associated with

medical treatments actually delivered to a plurality of patients. The medical treatment data includes a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter. This is further discussed in paragraph [00083]. Claim 23 differs from claim 1 in that it does not require the automatic supplying of the medical device with at least one revised treatment guideline. Instead, claim 23 includes a medication device 255 having an alarm and a library of appropriate parameter. See paragraph [000103]. The alarm is activated when a medical treatment guideline having parameters outside of the appropriate parameters is entered into the medication device. See paragraph [000115].

Independent claim 11 relates to a system 4 for analyzing medical treatment data to determine medical treatment guidelines associated with medication delivered to a patient by medication administration device 255 (see Figs. 1, 2 and 8). The system comprises a plurality of medication administration devices 255 of delivering medication to a plurality of patients (see Fig. 8, and paragraph [00082]). A memory 250 is associated with each medication administration device 255 for storing medical treatment data associated with the medication actually delivered to each of the plurality of patients, this medical treatment data including patient identification data, medication identification data and medication administration device operating parameters. See paragraphs [00081] – [00083].

A central processor 265 is configured to receive medical treatment data from each of the medication administration devices 255. See Fig. 8 and paragraph [00083]. A database 270 (Fig. 8.) is operatively connected to the central processor 265 for storing preestablished medical treatment guidelines representing acceptable values for the medical administration device operating parameters. See paragraph [00086]. Means are provided for communicating medical treatment data from the medication administration device 255 to the central processor 265. These means includes a communication system 5 (see paragraph [00043] and Fig. 8). The communication system 5 is

described, for example, as a local area network, a wide area network, intranet or internet based, or some other telecommunications network designed to carry signals in communications between the various information systems in the facility.

Means are provided to update the treatment guidelines in the medical devices. These means include the medical treatment data analysis system 4 and the processor 265.

The processor 265 is configured to compile from the medical treatment data a plurality of parameter values associated with a selected medication administration device operating parameter, analyze the compiled parameter values, and determine a medical guideline in accordance with the analysis, the medical treatment guideline representing acceptable values for the selected parameters. See paragraphs [00081] – [00084].

Independent claim 12 relates to a method for analyzing medical treatment data associated with medical treatments for a plurality of patients to determine the medical treatment guideline. As discussed at paragraph [00082], medical treatment data associated with medical treatments actually delivered to a plurality of patients are communicated. The medical treatment data is communicated via network 5, memory 250 of the medication administration device 255. Medical treatment data includes a plurality of treatment parameters for each of the plurality of patients and treatment parameter values associated with each treatment parameter. See paragraph [00081]. From the medical treatment data, a plurality of treatment parameter values associated with a selected treatment parameter are compiled. The compiled treatment parameter values are analyzed, and a revised medical treatment guideline is determined in accordance with the analysis. This medical treatment guideline represents acceptable values for the selected treatment parameter. See paragraph [00083]. The revised medical treatment guideline is provided to the medical device 255 from a remote location. See Fig. 8, which shows the

processor 265 remotely located from the medication administration device 255 and coupled by the communication system 5.

VI. GROUNDS OF REJECTION TO BE REVIEWED BY APPEAL

Whether claims 1-6, 8-17 and 19-23 are unpatentable over 35 U.S.C. §102(b) as being anticipated by Bocionek et al. (hereinafter "Bocionek").

VII. ARGUMENT

Examiner's Position

In the Final Office Action, the Examiner rejected claims 1-6, 8-17 and 19-23 under 35 U.S.C. §102(b) as being anticipated by Bocionek. The Examiner considered Bocionek as teaching a system for analyzing medical treatment data associated with medical treatment from a plurality of patients to determine a medical treatment guideline based on treatment administered to a plurality of patients and for at least updating one medical device, such as the infusion pump 85, with a guideline. The Examiner referred to paragraphs [0020], [0027], [0030] as showing the updating of the medical device with the guideline. The database 75 was said to store medical treatment data associated with medical treatments delivered to a plurality of patients. A processor connected to the database is said to be configured to compile from the medical treatment data a plurality of treatment parameter values associated with the selected treatment parameter, analyze the values and determine a treatment guideline representing acceptable values for the selected parameter, such as potential drug interactions [0022]. The decision functions 15 and 17 were said to automatically supply a medical device such as an infusion pump with an optimized drug dosage.

Appellant's Position:

In Applicant's arguments, the majority of the points raised are applicable to each of the independent claims. If further distinctions are to be made, such distinctions will be highlighted for the individual independent claims.

In each of the independent claims 1, 11 and 12, a processor determines a medical treatment guideline based upon the medical treatment data associated with the medication actually being delivered to a plurality of patients. The processor determines medical treatment guidelines in accordance with an analysis based upon the received data. The medical devices are updated with the

treatment guidelines. It is respectfully submitted that Bocionek fails to provide such a revised medical treatment guideline to the medical devices. In other words, Bocionek fails to disclose "a processor… configured to … automatically supply the medical device with at least one revised treatment guideline," as recited in independent claim 1, for example. Instead, Bocionek discloses a "device controller… in conjunction with the decision functions [which] intelligently controlled devices…" (Bocionek, [0027]). The thrust of Applicant's argument is that control of a device as described in Bocionek is very different from, (patentably so) the automatic supplying of the medical device with a revised treatment guideline, such as provided in independent claims 1, 11 and 12.

Bocionek discloses decision functions which "determine optimal drug dosage to be applied by an infusion pump using a control mechanism", again at paragraph [0027] of Bocionek. This refers to a particular instance of controlling in Bocionek, where an infusion pump is controlled by a control mechanism according to decision functions. The infusion pump itself is not supplied with a revised treatment guideline. In other words, the control of the device is not the same as providing a medical device with a revised treatment guideline. The "optimal drug dosage to be implied by an infusion pump" in Bocionek clearly shows that the device in Bocionek is receiving an instruction, rather than a guideline.

In order to support a case of anticipation under 35 U.S.C. §102, each and every element of the claimed invention must be identically disclosed in a single prior art reference. It is respectfully submitted, for at least the reasons given above, that Bocionek fails to disclose each element of independent claim 1. Dependent claims 2-6, 8-10 and 22 all depend from independent claim 1. Therefore, dependent claims 2-6, 8-10 and 22 therefore cannot be anticipated by Bocionek, since they inherit the patentability of claim 1.

The Examiner considers that the broadest reasonable definition for "guideline" is that of any guide of a future course of action. However, even assuming the Examiner's broadest reasonable interpretation is adopted, a guide to a future course of action is not the same thing as the actual control of such action.

It is respectfully submitted that the medical treatment devices, such as the infusion pump 85 or ventilator 83 of Bocionek do not receive treatment guidelines as required by the claims. The systems are said to be controlled by the automated device controllers 31. Control is not the same thing as being provided with guidelines. This also goes towards the contention by Applicant that the optimal drug dosage to be implied by an infusion pump in Bocionek clearly shows that the device of Bocionek is receiving an instruction and not a guideline. It is respectfully that as is commonly understood, guidelines are considered to be limits within which different courses may be followed, as long as those courses fall within those limits. A specific control or instruction, by contrast, does not admit of variation from the specific parameter. In the application, the treatment guidelines provided to the medical device allow the medical device to be operated at the point of care somewhere within the parameters provided by the guidelines. A remote control of the medical device in accordance with an instruction sent by the device controller 31, as in Bocionek, admits of no such flexibility within guidelines. There is nothing in Bocionek that show supplying revised treatment guidelines to any of the medical devices. Instead, they are merely controlled by the CCIS application 10. The CCIS databases are central databases, and not distributed. Hence, there is no supplying of medical devices with revised treatment guidelines.

Claims 11 and 12 contain similar limitations with respect to claims 1 and 11. With respect to claim 11, means are provided to update treatment guidelines in the medical devices. Bocionek fails to disclose such a system. Instead, Bocionek teaches "modules and function [that] are advantageously

able to access and update patient record information". Bocionek, [0017]. These modules and functions are different than the "means to update treatment guidelines in the medical devices," recited in independent claim 11. The modules and functions in Bocionek update patient records, rather than medical devices, and the updating does not involve treatment guidelines. In reviewing claims for anticipation under 35 U.S.C. §102, containing means plus function limitations, identity of function must be found as well as such equivalence disclosed in the specification. In this case, the identity of function is not provided since Bocionek update patient records, rather than medical devices, and the updating does not involve treatment guidelines. For at least these reasons, in addition to those discussed above, Bocionek does not contain each and every element of independent claim 11. Furthermore, since dependent claim 21 depends from independent claim 11, dependent claim 21 cannot be anticipated by Bocionek since it inherits the patentability claim 11.

In addition to the earlier arguments with respect to claim 1, independent claim 12 recites a "method comprising… providing the revised medical treatment guideline to a medical device from a remote location." Bocionek fails to disclose such a method. Bocionek instead teaches a "CCIS application [, which] stores… medical parameters together with any treatment outcome data in local or remote databases for subsequent analysis." (Bocionek [0029]). The "CCIS application also adoptively updates… the analysis system based on stored data including treatment outcome data." (Bocionek [, 0029]). In Bocionek the information is not provided to a medical device, as recited in independent claim 12.

Furthermore, impendent claim recites "analyzing the compiled treatment parameter values; determining a revised medical treatment guideline in accordance with the analysis, the medical treatment guideline representing acceptable values for the selected treatment parameter." The "medical parameters" and "treatment outcome" in Bocionek are different from the "medical treatment

guideline," recited in claim 12. The medical parameters in Bocionek are "electro-cardiograph data, electro and encephalograph data, ventilation data, blood oxygen data, blood pressure data, infusion pump data and pulse data." (Bocionek, [0028]). Thus, the medical parameter and treatment outcome data in Bocionek are merely data, rather than a "guideline representing acceptable values for the selected treatment parameter," as recited and required by independent claim 12. Moreover, the medical parameters and treatment outcome data in Bocionek are obtained in connection with monitoring patients from patient monitoring devices (see Bocionek [0028]), whereas the guideline in independent claim 12 is a revised medical treatment guideline in accordance with the analysis.

For at least these reasons, Bocionek does not contain each and every element of independent claim 12. Therefore, Bocionek fails to anticipate independent claim 12 and those claims dependent therefrom. Dependent claims 13-17, 19 and 20 depend from independent claim 12 and inherit its patentability. Therefore, these dependent claims cannot be anticipated by Bicionek, for at least the reasons that Bocionek does not anticipate independent claim 12.

Independent claim 23 recites a system comprising "a medication device having an alarm and a library of appropriate parameters, the alarm being activated when a medical treatment guideline having parameters outside of the appropriate parameters is input into the medication device." Bocionek fails to disclose such a system. Instead, Bocionek teaches an "alarm function [which] generates an alarm based on vital signs collected from patient monitoring units." The alarm in Bocionek is different from the alarm in independent claim 23. The alarm in independent claim 23 is activated "and a medical treatment guideline having parameters outside of the appropriate parameters is input into a medication," whereas the alarm in Bocionek is activated "based on vital signs collected from patient monitoring units." In the Advisory Action, the Examiner stated that at [0026], Bocionek states that alarm function 29 generates an alarm based on individual, composite, or weighted composite vital

signs from units 81-87 ("medication device"). However, this is not the same as an alarm being activated when a medical treatment guideline having parameters outside of the appropriate parameters is inputted into the medication device. It is only an alarm of vital signs, and not medical treatment guideline violations. Furthermore, the Examiner did not respond to the Applicant's argument regarding a library of appropriate parameters. The Bocionek system is a centralized system, not one in which a medical device system has been shown to have a library of appropriate parameters and medical treatment guidelines. For these reasons, Bocionek fails to disclose each and every element of the claimed independent claim 23.

Since each of the claims 1-6, 8-10 and 19-23 recite systems and methods that are patentably distinct from the disclosed systems and methods of Bocionek, the present invention as currently claimed should be considered patentable over Bocionek.

VIII. Conclusion

Since each of the independent claims is patentably distinct from Bocionek, which has not been proven to identically disclose each and every element of the claimed invention, the rejection of claims 1-6, 8-17 and 19-23 under 35 U.S.C. §102 should be reconsidered and withdrawn. Such action is courteously solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. § 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

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CLAIMS APPENDIX

1. A system for analyzing medical treatment data associated with medical treatments for a plurality of patients to determine a medical treatment guideline based on actual treatment of a plurality of patients, and for updating at least one medical device that is in communication with the system with the guideline, the system comprising:

a memory for storing medical treatment data associated with medical treatments actually delivered to a plurality of patients, the medical treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter; and

a processor operatively connected to the memory and configured to compile from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyze the compiled treatment parameter values, and determine a medical treatment guideline in accordance with the analysis, the medical treatment guideline representing acceptable values for the selected treatment parameter, and to automatically supply the medical device with at least one revised treatment guideline.

2. The system of claim 1 wherein the analysis of the compiled treatment parameter values includes providing a statistical distribution of the compiled treatment parameter values.

3. The system of claim 1 further comprising:

a database for storing preestablished medical treatment guidelines; and

wherein the processor is further configured to compare the compiled treatment parameter values to the acceptable values for the treatment parameter in the corresponding preestablished medical treatment guideline for the selected parameter.

4. The system of claim 3 wherein the processor is further configured to adjust the acceptable values for the selected treatment parameter in the preestablished medical treatment guideline as a result of the comparison to create an updated medical treatment guideline for the selected treatment parameter.

5. The system of claim 3 wherein the processor is further configured to generate a report of the comparison.

6. The system of claim 1 wherein the processor is further configured to generate a report of the analysis.

7. (Canceled)

8. The system of claim 1 wherein the processor is further configured to integrate the determined medical treatment guideline into a database of preestablished medical treatment guidelines.

9. The system of claim 1 wherein the processor is further configured to determine a medical treatment guideline in accordance with the analysis, the medical treatment guideline representing an optimum value for the selected parameter.

10. The system of claim 1 wherein the medical treatment data includes patient physiological data, and the processor is further configured to analyze the. treatment parameter values of the selected treatment parameter with respect to the corresponding physiological data for each of the plurality of patients and to determine a medical treatment guideline in accordance with the analysis, the medical treatment guideline representing at least one optimum value for the selected treatment parameter.

11. A system for analyzing medical treatment data to determine medical treatment guidelines associated with medication delivered to a patient by a medication administration device, the system comprising:

a plurality of medication administration devices for delivering medication to a plurality of patients;

a memory associated with each medication administration device for storing medical treatment data associated with the medication actually delivered to each of the plurality of patients, the medical treatment data including patient identification data, medication identification data and medication administration device operating parameters;

a central processor configured to receive medical treatment data from each of the medication administration devices;

a database operatively connected to the central processor for storing preestablished medical treatment guidelines representing acceptable values for the medical administration device operating parameters;

means for communicating medical treatment data from the medication administration device to the central processor; and

means to update treatment guidelines in the medical devices;

wherein the processor is configured to compile from the medical treatment data a plurality of parameter values associated with a selected medication administration device operating parameter, analyze the compiled parameter values, and determine a medical treatment guideline in accordance

with the analysis, the medical treatment guideline representing acceptable values for the selected parameter.

12. A method for analyzing medical treatment data associated with medical treatments for a plurality of patients to determine a medical treatment guideline, the method comprising:

communicating medical treatment data associated with medical treatments actually delivered to a plurality of patients, the medical treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter;

compiling from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter;

analyzing the compiled treatment parameter values;

determining a revised medical treatment guideline in accordance with the analysis, the medical treatment guideline representing acceptable values for the selected treatment parameter; and

providing the revised medical treatment guideline to a medical device from a remote location.

13. The method of claim 12 wherein analyzing the treatment parameter values includes providing a statistical distribution of the treatment parameter values for the selected treatment parameter.

14. The method of claim 12 further comprising:

storing preestablished medication treatment guidelines in a database; and

comparing the compiled treatment parameter values to the acceptable values for the treatment parameter in the corresponding preestablished medical treatment guideline for the selected parameter.

15. The method of claim 14 further comprising:

adjusting the acceptable values for the selected treatment parameter in the preestablished medical treatment guideline as a result of the comparison to create an updated medical treatment guideline for the selected treatment parameter.

16. The method of claim 14 further comprising:

generating a report of the comparison.

17. The method of claim 12 further comprising:

generating a report of the analysis.

18. (Canceled)

19. The method of claim 12 further comprising:

integrating the determined medical treatment guideline into a database of preestablished medical treatment guidelines.

20. The method of claim 12 further comprising:

determining a medical treatment guideline in accordance with the analysis, the medical treatment guideline representing an optimum value for the selected parameter in accordance with the analysis.

21. A system as described in claim 11, wherein the means to update treatment guidelines in the medical devices comprises means to automatically update the treatment guidelines in the medical devices.

22. A system as described in claim 1, wherein the medical device is an infusion pump.

23. A system for analyzing medical treatment data associated with medical treatments for a plurality of patients to determine a medical treatment guideline based on actual treatment of a plurality of patients, the system comprising:

a memory for storing medical treatment data associated with medical treatments delivered to a plurality of patients, the medical treatment data including a plurality of treatment parameters for each of the plurality of patients and a treatment parameter value associated with each treatment parameter;

a processor operatively connected to the memory and configured to compile from the medical treatment data a plurality of treatment parameter values associated with a selected treatment parameter, analyze the compiled treatment parameter values, and determine a medical treatment guideline in accordance with the analysis, the medical treatment guideline representing acceptable values for the selected treatment parameter; and

a medication device having an alarm and a library of appropriate parameters , the alarm being activated when a medical treatment guideline having parameters outside of the appropriate parameters is input into the medication device.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.